

### REMARKS

This Amendment is submitted in response to the Office Action mailed on March 18, 2002. Claims 10-12 and 18 have been amended, claims 13-17 and 19 have been canceled without prejudice or disclaimer and claims 20-26 have been added. Claims 1-12, 18 and 20-26 remain in the present application. Applicant's counsel appreciates the courtesy extended by Examiner Bockelman during the personal interview conducted on May 22, 2002. Applicant notes and appreciates Examiner's indication of the allowability of claims 2, 5-9 and 14. In view of the foregoing amendments, as well as the following remarks, Applicant respectfully submits that this application is in complete condition for allowance and request reconsideration of the application in this regard.

Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claim 19 stands rejected 35 U.S.C. § 102(b) as being anticipated by, or alternatively under 35 U.S.C. § 103(a), as being obvious over Mann et al., U.S. Patent No. 5,545,191. Claim 12 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Arnold, U.S. Patent No. 4,995,857. Claims 12 and 15-18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Bolling, U.S. Patent No. 6,299,575. Claims 1, 3-4 and 10-11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Arnold in view of Bolling. Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldowsky, U.S. Patent No. 5,924,975. Lastly, claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolling in view of Mann et al. While Applicant

traverses the rejections of claims 13-17 and 19, Applicant has canceled these claims without prejudice or disclaimer to accelerate prosecution of the present application. Therefore, the rejections of these claims are moot. For the reasons set forth below, Applicant submits that claims 1-12 and 18 are allowable and the rejections of these claims should be withdrawn.

By way of background, the present invention is directed to a heart assist device or system which is designed to provide effective assistance with cardiac output by unloading the heart. Blood is withdrawn from the left atrium by a pump and is discharged into a catheter or conduit which is connected for fluid communication with an artery, such as an axillary artery. The heart assist device is implanted in a patient through a non-invasive surgical procedure so the system is only slightly more complex to insert than a pacemaker.

As recited in original independent claim 1 and amended independent claim 11, a method of supplementing the blood flow from the heart of a patient using a pump assist system comprises the steps of directing a first conduit into the left side of the heart, coupling a second conduit in fluid communication with a superficial artery of the patient, connecting a pump between the first and second conduits, implanting the pump in a superficial, subcutaneous area of the patient, suctioning blood from the left side of the heart through the first conduit and into the pump, and expelling the blood from the pump into the second conduit and the superficial artery. Amended independent claim 11 further recites that the pump is implanted in a superficial, subcutaneous chest region of a patient.

The primary Arnold reference is directed to a heart assist device having a pump described as being sewn with thread to the wall of the left atrium (Fig. 1), anchored to a portion of the patient's skeletal frame (Figs. 2(a) and 2(b)) or used temporarily outside of the patient's body following open-heart surgery (Figs. 5-8), each part of an invasive surgical procedure. As properly recognized by Examiner, Arnold is completely silent with respect to implanting the pump in a superficial, subcutaneous region of the patient as claimed by Applicant.

Bolling is directed to an extracardiac pumping system for supplementing the circulation of blood through a patient without any component thereof being connected to a patient's heart. The pump (32) may be placed in fluid communication with a patient's left axillary artery (24) and femoral artery (26) and may be implanted in the groin area of the patient to supplement the circulation of blood through the patient. Bolling is completely silent with respect to connecting the pump to the left side of the heart to unload the heart as claimed by Applicant.

Applicant respectfully submits that there is no teaching or suggestion to hypothetically combine Arnold and Bolling as sought in the rejections and the rejections of independent claims 1 and 11 should therefore be withdrawn. In particular, Arnold teaches a pump system that is either used only temporarily outside of the body or, when used permanently within the body, the pump is connected to the left atrium or skeletal frame of the patient through an invasive surgical procedure. Moreover, the pump system of Bolling is directed to a completely different problem of supplementing the circulation of blood through the

patient, and the pump system does not provide effective assistance with cardiac output by unloading the heart since it is not connected to the left atrium of the patient's heart. Rather, in the pump system of Bolling, the heart must work to expel blood from the left atrium, and the pump system of Bolling merely aids in circulating the blood through the patient after it has been pumped by the heart.

Applicant respectfully submits that the prior art of record does not teach or suggest implanting a pump superficially and subcutaneously within a patient for suctioning blood from the left side of the heart and expelling the blood into a superficial artery of a patient as claimed by Applicant and the rejections of independent claims 1 and 11 should be withdrawn. Moreover, as claims 2-10 and 20-26 depend from allowable independent claims 1 and 11, respectively, and further as each of these claims recites a combination of features not taught or suggested by the prior art of record, Applicant submits that these claims are allowable as well.

Applicant has amended independent claim 12 to include the allowable subject matter of claim 14. Accordingly, Applicant submits that amended independent claim 12 is allowable.

Applicant has amended independent claim 18 to more sharply define the claimed invention over the prior art of record. In particular, Applicant has amended independent claim 18 to recite that the return conduit is coupled with an outlet of the pump and another portion of the system for returning a portion of the blood expelled by the pump from the return conduit to the other portion of the

system. As fully described in Applicant's disclosure on page 12, lines 3-23, the return conduit provides a cleansing or rinsing function to prevent stagnation or blood clot formation within the interior of the pump. Applicant respectfully submits that the prior art of record does not teach or suggest a return conduit coupled with an outlet of the pump and another portion of the system as claimed and the rejection should be withdrawn.

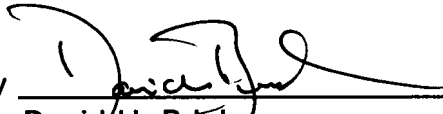
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

#### Conclusion

In view of the foregoing response including the amendments and remarks, this application is submitted to be in complete condition for allowance and early notice to this affect is earnestly solicited. If there is any issue that remains which may be resolved by telephone conference, the Examiner is invited to contact the undersigned in order to resolve the same and expedite the allowance of this application.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

By   
David H. Brinkman  
Reg. No. 40,532

2700 Carew Tower  
441 Vine Street  
Cincinnati, OH 45202  
(513) 241-2324 - Voice  
(513) 421-7269 - Facsimile